

10/546829

DT09 Rec'd PCT/PTO 25 AUG 2005

Written Reply according to PCT Article 34

5. Contents of Reply

The examiner, in the written opinion, quoted the references 1 and 2 and showed his opinion that the claims 1 to 4 of the present invention have no inventive step. To argue against this opinion, the inventors show an opinion as follows. Claims were amended at the same time to clarify the difference between the present invention and the references.

The invention of claims 1 to 3 (claim 4 was deleted) relates to a cancer treatment drug comprising a transcriptional factor as an effective component, which induces apoptosis of cancer cells exclusively. It is clear that the drug of the present invention has such effect (the drug induces apoptosis of cancer cells) from the result shown in Example 1 (Fig. 9), where the expression of p53 or a mutated type of p53 and clathrin heavy chains in cancer cells enhances the transcriptional activity of p53AIP1 promoter,

If a complex comprising p53 or a mutated type of p53 and clathrin heavy chains existed spontaneously in cancer cells as a cancer treatment drug (or existed spontaneously as a cancer treatment drug comprising a transcriptional factor inducing apoptosis in cancer cells) and had equivalently effective as a cancer treatment drug of claims 1 to 3 of the present invention, as the opinion of the examiner, it could not be explained rationally that, in Figure 9, the transcriptional activity from p53AIP1 promoter (vertical axis) kept to a low level in the first column from the left (Clathrin HC-/p53-).

The present invention relates to a cancer treatment drug and a method for cancer treatment. The cancer treatment drug, employing a factor comprising p53 or a mutated type of p53 and clathrin heavy chains, is able to treat cancer by injecting the factor to cancer cells and to induce apoptosis of cancer cells. The constitution of the present invention and the effect of the present invention are absolutely not described in the references 1 or 2.

Because of the above reasons, the inventors believe that the present invention is not the invention led easily from the references. Therefore, the inventors sincerely ask to examine this invention again.

6. List of attached documents.

- (1) Description: pages 6, 8, 9; total 3 pages
- (2) Claims; total 1 page

Amendment according to PCT Article 34

4. Object of Amendment

Descriptions and Claims

5. Contents of Amendment

- (1) The inventors amend Example 1 to Test Example 5 in page 6 of descriptions, Test Example 5 to Test Example 6 in page 7 of descriptions and Example 2 to Example 1 in page 8 of descriptions.
- (2) The inventors amend “A transcriptional factor” in claims 1 to 3 to “A cancer treatment drug”, delete claim 4 and add new claims 5 and 6.

6. List of Attached Documents

- (1) Descriptions: pages 6, 8, 9; total 3 pages
- (2) Claims: total 1 page

Claims:

1. (amended) A cancer treatment drug comprising a transcriptional factor as an effective component, which comprises p53 or a mutated type p53, wherein one or more amino acids are deleted, substituted or added with respect to the amino sequence of p53, and clathrin heavy chains.
2. (amended) The cancer treatment drug of claim 1, wherein at least the serine residue at amino acid position 46 is substituted in said mutated type p53.
3. (amended) The cancer treatment drug of claim 2, wherein said serine residue at amino acid position 46 is substituted to phenylalanine.
4. (deleted)
5. (amended) A method for treating cancer comprising injecting a transcriptional factor, which comprises p53 or a mutated type p53, wherein one or more amino acids are deleted, substituted or added with respect to the amino sequence of p53, and clathrin heavy chains to a cancer cell, or injecting clathrin heavy chains to a cancer cell.
6. (new) The method for treating cancer of claim 5, wherein at least the serine residue at amino acid position 46 is substituted in said mutated type p53.
7. (new) The method for treating cancer of claim 6, wherein said serine residue at amino acid position 46 is substituted to phenylalanine.